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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,991	07/26/2001	John Paul McGee	JANS-0008	7988

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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,991

Applicant(s)

MCGEE ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-7,9-15,17,18,20-22 and 26-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-7,9-15,17,18,20-22 and 26-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |



DETAILED ACTION

Examiner acknowledges receipt of request for extension of time, amendment and remarks filed 03/02/05. Claims 4-7, 9-15, 17, 18, 20-22 and 26-30 are pending.

Claim Rejections - 35 USC § 112

1. The rejection of claims 5-7, 14, 15 and 17-22 under 35 U.S.C. 112, second paragraph, as being indefinite because claim 5 was of an improper Markush format is withdrawn because claim 5 is amended and is of the proper Markush format.
2. Claims 11-15, 17, 18 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites, “comprising” for a Markush claim and the claim is thus of an improper Markush format. The claim may read ---consisting of--- in place of the comprising to comply with the Markush type claim.

Claim 28 defines dementia as “nicotine cessation and withdrawal” and it is not clear how nicotine cessation and withdrawal is dementia.

Claim Objections

The objection of claim 19 under 37 CFR 1/75 (c) as being of improper form is withdrawn because claim 19 is canceled.

Claim Rejections - 35 USC § 102

3. The rejection of claims 2-6, 10, 11, 17, 22, 23 and 25 under 35 U.S.C. 102(b) as being anticipated by Davis et al. (CA 1326632) is withdrawn because the amended claim 10 requires

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that the core comprise an inert core upon which is layered the galantamine HBr and the film forming polymer.

Claim Rejections - 35 USC § 103

4. The rejection of claims 7, 12, 14, 15, 18-21, 24 and 26-29 under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US 4,663,318) is withdrawn because Davis does not disclose the requirement of claim 10 that the water soluble film forming polymer and galantamine be layered onto inert spheres.

5. Claims 4-7, 9-15, 17, 18, 20-22 and 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al. (US 5,576,022) in view of Davis et al. (CA 1326632, previously cited).

Yang discloses a controlled release formulation that comprises an immediate release core that comprises nonpareil seeds, tacrine and binding agent, a sealing layer or sustained release layer over the immediate release pellets (abstract). The sustaining layer comprises water-insoluble polymer (claim 2), water-soluble polymer (claim 1); and polyethylene glycol plasticizing agent and povidone (claims 4 and 7). An example of the water-insoluble polymer is ethyl cellulose (claim 11) and an example of water soluble polymer in the sustaining layer is hydroxypropyl methylcellulose (claim 14). Tacrine is a known cholinesterase-inhibiting agent that is used to treat symptoms Alzheimer's patients (column 1, lines 27 and 28; column 4, lines 14-16).

Although Yang discloses the formulation of the instant invention, the active agent is tacrine instead of galantamine. Galantamine is also acetyl cholinesterase inhibitor that can be

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used to treat the symptoms of Alzheimer's. Davis discloses sustained release formulation for the treatment of Alzheimer's disease and the formulation comprises particles of galantamine (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the tacrine formulation of Yang to patients in need thereof to treat the symptom of Alzheimer's. Since galantamine and tacrine are both used to treat the symptoms of Alzheimer's, a formulation according to Yang prepared with galantamine would be expected to treat the symptoms of Alzheimer's when administered to a patient in need thereof. The motivation comes from the art recognized equivalent utility of galantamine or other acetylcholine esterase and tacrine in the treatment of symptoms in Alzheimer's patients.

Chen et al. (US 6,183,777) is equivalent to Yang. Chen discloses controlled release tacrine dosage form that comprises a core, coated on the core is an active inner layer comprising tacrine, a release-controlling layer comprising one or more release controlling film forming polymer, and an active overcoat that comprises tacrine and a binder (abstract; column 4, line 13 to column 5 line 65). The film forming polymers are the same as those recited in the claims namely water-insoluble polymers in the release controlling layer and water-soluble polymers in the active core layer (column 5, lines 35-42 and lines 47-53). Just as is discussed above, it would be obvious to substitute the galantamine of Davis for the tacrine of Chen and expect to treat Alzheimer's disease in patients in need thereof.

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification including the claims.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read "B. Fubara", is written over the printed name and title of the examiner.